

AMENDMENTS TO THE CLAIMS

In the Claims:

Claims 1-69 were previously cancelled and claims 70-226 were previously presented in the Preliminary Amendment filed on December 27, 2001. Please amend claims 70, 71, 72, 101, 102, 132, 133, 163, 164, 194 and 195 as follows:

Claims 1-69 (Cancelled).

70. (Currently Amended) A method of treating a patient with a therapeutic adenovirus composition, comprising:

- a) ~~preparing obtaining~~ a therapeutic adenovirus composition ~~that has been prepared~~ by a process that includes:
 - i) growing host cells in a media;
 - ii) providing nutrients to said host cells;
 - iii) infecting said host cells with an adenovirus;
 - iv) lysing said host cells to provide a lysate;
 - v) purifying adenovirus from said lysate to provide therapeutic adenovirus;
 - vi) formulating said therapeutic adenovirus to provide a therapeutic adenovirus composition;
- b) administering said therapeutic adenovirus composition to a patient.

71. (Currently Amended) The method of claim 70, wherein the therapeutic adenovirus comprises 70% +/- 10% of the starting PFU of the lysate of step iv.

72. (Currently Amended) The method of claim 70, wherein the therapeutic adenovirus comprises a substantially purified therapeutic adenovirus composition.

73. (Previously Presented) The method of claim 70, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.8 ng/ml.

74. (Previously Presented) The method of claim 70, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.2 ng/ml.

75. (Previously Presented) The method of claim 70, wherein the therapeutic adenovirus composition has an A_{260}/A_{280} ratio of between about 1.2 and 1.3.

76. (Previously Presented) The method of claim 70, wherein the therapeutic adenovirus composition has an A_{260}/A_{280} ratio of 1.27 +/- 0.03.

77. (Previously Presented) The method of claim 70, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.8 ng/ml and an A_{260}/A_{280} ratio of between about 1.2 and 1.3.

78. (Previously Presented) The method of claim 70, wherein the therapeutic adenovirus composition has a BSA content below the detection level of a western blot assay.

79. (Previously Presented) The method of claim 70, wherein the media is serum-free.

80. (Previously Presented) The method of claim 70, wherein the host cells are grown in a bioreactor.

81. (Previously Presented) The method of claim 70, wherein the host cells are grown on microcarriers.

82. (Previously Presented) The method of claim 70, wherein the host cells are provided nutrients by perfusion.

83. (Previously Presented) The method of claim 70, wherein the host cells are provided nutrients by fed batch.

84. (Previously Presented) The method of claim 70, wherein the host cells are provided nutrients by automated roller bottle.

85. (Previously Presented) The method of claim 70, wherein said therapeutic adenovirus composition comprises an adenoviral vector encoding an exogenous gene construct.

86. (Previously Presented) The method of claim 85, wherein said exogenous gene construct is operatively linked to a promoter.

87. (Previously Presented) The method of claim 86, wherein said promoter is SV40 IE, RSV LTR, β -actin, CMV IE, adenovirus major late, polyoma F9-1, or tyrosinase.

88. (Previously Presented) The method of claim 85, wherein said exogenous gene construct encodes a therapeutic gene.

89. (Previously Presented) The method of claim 88, wherein said therapeutic gene encodes antisense *ras*, antisense *myc*, antisense *raf*, antisense *erb*, antisense *src*, antisense *fms*, antisense *jun*, antisense *trk*, antisense *ret*, antisense *gsp*, antisense *hst*, antisense *bcl*, antisense *abl*, Rb, CFTR, p16, p21, p27, p57, p73, C-CAM, APC, CTS-1, *zac1*, scFV *ras*, DCC, NF-1, NF-2, WT-1, MEN-1, MEN II, BRCA1, VHL, MMAC1, FCC, MCC, BRCA2, IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, GM-CSF, G-CSF, thymidine kinase or p53.

90. (Previously Presented) The method of claim 88, wherein said therapeutic gene encodes p53.

91. (Previously Presented) The method of claim 70, wherein said therapeutic adenovirus composition is a replication-incompetent adenovirus.

92. (Previously Presented) The method of claim 91, wherein said replication-incompetent adenovirus composition is lacking at least a portion of the E1-region.

93. (Previously Presented) The method of claim 91, wherein said replication-incompetent adenovirus composition is lacking at least a portion of the E1A and/or E1B region.

94. (Previously Presented) The method of claim 70, wherein said host cells are capable of complementing replication.

95. (Previously Presented) The method of claim 70, wherein said host cells are 293 cells.

96. (Previously Presented) The method of claim 70, wherein said lysate is treated with a nuclease.

97. (Previously Presented) The method of claim 70, wherein said therapeutic adenovirus composition comprises a pharmaceutically acceptable buffer.

98. (Previously Presented) The method of claim 70, wherein said therapeutic adenovirus comprises a unit dose of between 10^3 and 10^{15} PFU/dose.

99. (Previously Presented) The method of claim 70, wherein said therapeutic adenovirus composition comprises a unit dose of between 10^{10} and 10^{14} PFU/dose.

100. (Previously Presented) The method of claim 70, wherein said patient is a cancer patient.

101. (Currently Amended) A method of treating a patient with a therapeutic adenovirus composition, comprising:

- a) ~~preparing~~ obtaining a therapeutic adenovirus composition ~~that has been prepared~~ by a process that includes:
 - i) growing host cells in a bioreactor or on a microcarrier;
 - ii) providing nutrients to said host cells ;
 - iii) infecting said host cells with an adenovirus;

- iv) lysing said host cells to provide a lysate;
 - v) purifying adenovirus from said lysate to provide therapeutic adenovirus;
 - vi) formulating said therapeutic adenovirus to provide a therapeutic adenovirus composition;
- b) administering said therapeutic adenovirus composition to a patient.

102. (Currently Amended) The method of claim 101, wherein the therapeutic adenovirus comprises 70% +/- 10% of the starting PFU of the lysate of step iv.

103. (Previously Presented) The method of claim 101, wherein the therapeutic adenovirus comprises a substantially therapeutic adenovirus composition.

104. (Previously Presented) The method of claim 101, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.8 ng/ml.

105. (Previously Presented) The method of claim 101, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.2 ng/ml.

106. (Previously Presented) The method of claim 101, wherein the therapeutic adenovirus composition has an A_{260}/A_{280} ratio of between about 1.2 and 1.3.

107. (Previously Presented) The method of claim 101, wherein the therapeutic adenovirus composition has an A_{260}/A_{280} ratio of 1.27 +/- 0.03.

108. (Previously Presented) The method of claim 101, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.8 ng/ml and an A_{260}/A_{280} ratio of between about 1.2 and 1.3.

109. (Previously Presented) The method of claim 101, wherein the therapeutic adenovirus composition has a BSA content below the detection level of a western blot assay.

110. (Previously Presented) The method of claim 101, wherein the media is serum-free.

111. (Previously Presented) The method of claim 101, wherein the host cells are grown in a bioreactor.

112. (Previously Presented) The method of claim 101, wherein the host cells are grown on microcarriers.

113. (Previously Presented) The method of claim 101, wherein the host cells are provided nutrients by perfusion.

114. (Previously Presented) The method of claim 101, wherein the host cells are provided nutrients by fed batch.

115. (Previously Presented) The method of claim 101, wherein the host cells are provided nutrients by automated roller bottle.

116. (Previously Presented) The method of claim 101, wherein said therapeutic adenovirus composition comprises an adenoviral vector encoding an exogenous gene construct.

117. (Previously Presented) The method of claim 116, wherein said exogenous gene construct is operatively linked to a promoter.

118. (Previously Presented) The method of claim 117, wherein said promoter is SV40 IE, RSV LTR, β -actin, CMV IE, adenovirus major late, polyoma F9-1, or tyrosinase.

119. (Previously Presented) The method of claim 116, wherein said exogenous gene construct encodes a therapeutic gene.

120. (Previously Presented) The method of claim 119, wherein said therapeutic gene encodes antisense *ras*, antisense *myc*, antisense *raf*, antisense *erb*, antisense *src*, antisense *fms*, antisense *jun*, antisense *trk*, antisense *ret*, antisense *gsp*, antisense *hst*, antisense *bcl*, antisense *abl*, Rb, CFTR, p16, p21, p27, p57, p73, C-CAM, APC, CTS-1, *zac1*, scFV *ras*, DCC, NF-1, NF-2, WT-1, MEN-1, MEN II, BRCA1, VHL, MMAC1, FCC, MCC, BRCA2, IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, GM-CSF, G-CSF, thymidine kinase or p53.

121. (Previously Presented) The method of claim 119, wherein said therapeutic gene encodes p53.

122. (Previously Presented) The method of claim 101, wherein said therapeutic adenovirus composition is a replication-incompetent adenovirus.

123. (Previously Presented) The method of claim 122, wherein said replication-incompetent adenovirus composition is lacking at least a portion of the E1-region.

124. (Previously Presented) The method of claim 122, wherein the replication-incompetent adenovirus composition is lacking at least a portion of the E1A and/or E1B region.

125. (Previously Presented) The method of claim 101, wherein said host cells are capable of complementing replication.

126. (Previously Presented) The method of claim 101, wherein said host cells are 293 cells.

127. (Previously Presented) The method of claim 101, wherein said lysate is treated with a nuclease.

128. (Previously Presented) The method of claim 101, wherein said therapeutic adenovirus composition comprises a pharmaceutically acceptable buffer.

129. (Previously Presented) The method of claim 101, wherein said therapeutic adenovirus composition comprises a unit dose of between 10^3 and 10^{15} PFU/dose.

130. (Previously Presented) The method of claim 101, wherein said therapeutic adenovirus composition comprises a unit dose of between 10^{10} and 10^{14} PFU/dose.

131. (Previously Presented) The method of claim 101, wherein said patient is a cancer patient.

132. (Currently Amended) A method of treating a patient with a therapeutic adenovirus composition, comprising:

- a) ~~preparing~~ obtaining a therapeutic adenovirus composition ~~that has been prepared~~ by a process that includes:
 - i) growing host cells in a media;
 - ii) providing nutrients to said host cells by perfusion or through a fed batch or roller bottle process;
 - iii) infecting said host cells with an adenovirus;
 - iv) lysing said host cells to provide a lysate;
 - v) purifying adenovirus from said lysate to provide therapeutic adenovirus;
 - vi) formulating said therapeutic adenovirus to provide a therapeutic adenovirus composition;
- b) administering said therapeutic adenovirus composition to a patient.

133. (Currently Amended) The method of claim 132, wherein the therapeutic adenovirus composition comprises 70% +/- 10% of the starting PFU of the lysate of step iv.

134. (Previously Presented) The method of claim 132, wherein the therapeutic adenovirus composition comprises a substantially therapeutic adenovirus composition.

135. (Previously Presented) The method of claim 132, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.8 ng/ml.

136. (Previously Presented) The method of claim 132, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.2 ng/ml.

137. (Previously Presented) The method of claim 132, wherein the therapeutic adenovirus composition has an A_{260}/A_{280} ratio of between about 1.2 and 1.3.

138. (Previously Presented) The method of claim 132, wherein the therapeutic adenovirus composition has an A_{260}/A_{280} ratio of 1.27 ± 0.03 .

139. (Previously Presented) The method of claim 132, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.8 ng/ml and an A_{260}/A_{280} ratio of between about 1.2 and 1.3.

140. (Previously Presented) The method of claim 132, wherein the therapeutic adenovirus composition has a BSA content below the detection level of a western blot assay.

141. (Previously Presented) The method of claim 132, wherein the media is serum-free.

142. (Previously Presented) The method of claim 132, wherein the host cells are grown in a bioreactor.

143. (Previously Presented) The method of claim 132, wherein the host cells are grown on microcarriers.
144. (Previously Presented) The method of claim 132, wherein the host cells are provided nutrients by perfusion.
145. (Previously Presented) The method of claim 132, wherein the host cells are provided nutrients by fed batch.
146. (Previously Presented) The method of claim 132, wherein the host cells are provided nutrients by automated roller bottle.
147. (Previously Presented) The method of claim 132, wherein said therapeutic adenovirus composition comprises an adenoviral vector encoding an exogenous gene construct.
148. (Previously Presented) The method of claim 147, wherein said exogenous gene construct is operatively linked to a promoter.
149. (Previously Presented) The method of claim 150, wherein said promoter is SV40 IE, RSV LTR, β -actin, CMV IE, adenovirus major late, polyoma F9-1, or tyrosinase.
150. (Previously Presented) The method of claim 149, wherein said exogenous gene construct encodes a therapeutic gene.
151. (Previously Presented) The method of claim 150, wherein said therapeutic gene encodes antisense *ras*, antisense *myc*, antisense *raf*, antisense *erb*, antisense *src*, antisense *fms*, antisense *jun*, antisense *trk*, antisense *ret*, antisense *gsp*, antisense *hst*, antisense *bcl*, antisense *abl*, Rb, CFTR, p16, p21, p27, p57, p73, C-CAM, APC, CTS-1, *zac1*, scFV *ras*, DCC, NF-1, NF-2, WT-1, MEN-1, MEN II, BRCA1, VHL, MMAC1, FCC, MCC, BRCA2, IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, GM-CSF, G-CSF, thymidine kinase or p53.

152. (Previously Presented) The method of claim 150, wherein said therapeutic gene encodes p53.
153. (Previously Presented) The method of claim 132, wherein said therapeutic adenovirus composition is a replication-incompetent adenovirus.
154. (Previously Presented) The method of claim 153, wherein said replication-incompetent adenovirus composition is lacking at least a portion of the E1-region.
155. (Previously Presented) The method of claim 153, wherein the replication-incompetent adenovirus composition is lacking at least a portion of the E1A and/or E1B region.
156. (Previously Presented) The method of claim 132, wherein said host cells are capable of complementing replication.
157. (Previously Presented) The method of claim 132, wherein said host cells are 293 cells.
158. (Previously Presented) The method of claim 132, wherein said lysate is treated with a nuclease.
159. (Previously Presented) The method of claim 132, wherein said therapeutic adenovirus composition comprises is pharmaceutically acceptable buffer.
160. (Previously Presented) The method of claim 132, wherein said therapeutic adenovirus composition comprises a unit dose of between 10^3 and 10^{15} PFU/dose.
161. (Previously Presented) The method of claim 132, wherein said therapeutic adenoviral composition comprises a unit dose of between 10^{10} and 10^{14} PFU/dose.

162. (Previously Presented) The method of claim 132, wherein said patient is a cancer patient.

163. (Currently Amended) A method of treating a patient with a therapeutic adenovirus composition, comprising:

- a) ~~preparing~~ obtaining a therapeutic adenovirus composition ~~that has been prepared~~ by a process that includes:
 - i) growing host cells in a media;
 - ii) providing nutrients to said host cells;
 - iii) infecting said host cells with an adenovirus;
 - iv) lysing said host cells by a lysis method other than freeze-thaw to provide a cell lysate;
 - v) purifying adenovirus from said cell lysate to provide therapeutic adenovirus;
 - vi) formulating said therapeutic adenovirus to provide a therapeutic adenovirus composition;
- b) administering said therapeutic adenovirus composition to a patient.

164. (Currently Amended) The method of claim 163, wherein the therapeutic adenovirus composition comprises 70% +/- 10% of the starting PFU of the lysate of step iv.

165. (Previously Presented) The method of claim 163, wherein the therapeutic adenovirus composition comprises a substantially therapeutic adenovirus composition.

166. (Previously Presented) The method of claim 163, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.8 ng/ml. -

167. (Previously Presented) The method of claim 163, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.2 ng/ml.

168. (Previously Presented) The method of claim 163, wherein the therapeutic adenovirus composition has an A_{260}/A_{280} ratio of between about 1.2 and 1.3.

169. (Previously Presented) The method of claim 163, wherein the therapeutic adenovirus composition has an A_{260}/A_{280} ratio of 1.27 +/- 0.03.

170. (Previously Presented) The method of claim 163, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.8 ng/ml and an A_{260}/A_{280} ratio of between about 1.2 and 1.3.

171. (Previously Presented) The method of claim 163, wherein the therapeutic adenovirus composition has a BSA content below the detection level of a western blot assay.

172. (Previously Presented) The method of claim 163, wherein the media is serum-free.

173. (Previously Presented) The method of claim 163, wherein the host cells are grown in a bioreactor.

174. (Previously Presented) The method of claim 163, wherein the host cells are grown on microcarriers.

175. (Previously Presented) The method of claim 163, wherein the host cells are provided nutrients by perfusion.

176. (Previously Presented) The method of claim 163, wherein the host cells are provided nutrients by fed batch.

177. (Previously Presented) The method of claim 163, wherein the host cells are provided nutrients by automated roller bottle.

178. (Previously Presented) The method of claim 163, wherein said therapeutic adenovirus composition comprises an adenoviral vector encoding an exogenous gene construct.

179. (Previously Presented) The method of claim 178, wherein said exogenous gene construct is operatively linked to a promoter.

180. (Previously Presented) The method of claim 179, wherein said promoter is SV40 IE, RSV LTR, β -actin, CMV IE, adenovirus major late, polyoma F9-1, or tyrosinase.

181. (Previously Presented) The method of claim 178, wherein said exogenous gene construct encodes a therapeutic gene.

182. (Previously Presented) The method of claim 181, wherein said therapeutic gene encodes antisense *ras*, antisense *myc*, antisense *raf*, antisense *erb*, antisense *src*, antisense *fms*, antisense *jun*, antisense *trk*, antisense *ret*, antisense *gsp*, antisense *hst*, antisense *bcl*, antisense *abl*, Rb, CFTR, p16, p21, p27, p57, p73, C-CAM, APC, CTS-1, *zac1*, scFV *ras*, DCC, NF-1, NF-2, WT-1, MEN-1, MEN II, BRCA1, VHL, MMAC1, FCC, MCC, BRCA2, IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, GM-CSF, G-CSF, thymidine kinase or p53.

183. (Previously Presented) The method of claim 181, wherein said therapeutic gene encodes p53.

184. (Previously Presented) The method of claim 163, wherein said therapeutic adenovirus composition is a replication-incompetent adenovirus.

185. (Previously Presented) The method of claim 184, wherein said replication-incompetent adenovirus composition is lacking at least a portion of the E1-region.

186. (Previously Presented) The method of claim 184, wherein the replication-incompetent adenovirus composition is lacking at least a portion of the E1A and/or E1B region.

187. (Previously Presented) The method of claim 163, wherein said host cells are capable of complementing replication.

188. (Previously Presented) The method of claim 163, wherein said host cells are 293 cells.

189. (Previously Presented) The method of claim 163, wherein said lysate is treated with a nuclease.

190. (Previously Presented) The method of claim 163, wherein said therapeutic adenovirus composition comprises is pharmaceutically acceptable buffer.

191. (Previously Presented) The method of claim 163, wherein said therapeutic adenovirus composition comprises a unit dose of between 10^3 and 10^{15} PFU/dose.

192. (Previously Presented) The method of claim 163, wherein said therapeutic adenovirus composition comprises a unit dose of between 10^{10} and 10^{14} PFU/dose.

193. (Previously Presented) The method of claim 163, wherein said patient is a cancer patient.

194. (Currently Amended) A method of treating a patient with a therapeutic adenovirus composition, comprising:

- a) preparing ~~obtaining~~ a therapeutic adenovirus composition ~~that has been prepared~~ by a process that includes:
 - i) growing host cells in a media;
 - ii) providing nutrients to said host cells;
 - iii) infecting said host cells with an adenovirus;

- iv) lysing said host cells to provide a lysate;
 - v) purifying adenovirus from said lysate by a method that includes at least one chromatography step, without the use of cesium chloride density gradient centrifugation capable of providing therapeutic adenovirus;
 - vi) formulating said therapeutic adenovirus to provide a therapeutic adenovirus composition;
- b) administering said therapeutic adenovirus composition to a patient.

195. (Currently Amended) The method of claim 194, wherein the therapeutic adenovirus composition comprises 70% +/- 10% of the starting PFU of the lysate of step iv.

196. (Previously Presented) The method of claim 194, wherein the therapeutic adenovirus composition comprises a substantially therapeutic adenovirus composition.

197. (Previously Presented) The method of claim 194, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.8 ng/ml.

198. (Previously Presented) The method of claim 194, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.2 ng/ml.

199. (Previously Presented) The method of claim 194, wherein the therapeutic adenovirus composition has an A_{260}/A_{280} ratio of between about 1.2 and 1.3.

200. (Previously Presented) The method of claim 194, wherein the therapeutic adenovirus composition has an A_{260}/A_{280} ratio of 1.27 +/- 0.03.

201. (Previously Presented) The method of claim 194, wherein the therapeutic adenovirus composition has a contaminating nucleic acid concentration of less than 0.8 ng/ml and an A_{260}/A_{280} ratio of between about 1.2 and 1.3.

202. (Previously Presented) The method of claim 194, wherein the therapeutic adenovirus composition has a BSA content below the detection level of a western blot assay.

203. (Previously Presented) The method of claim 194, wherein the media is serum-free.

204. (Previously Presented) The method of claim 194, wherein the host cells are grown in a bioreactor.

205. (Previously Presented) The method of claim 194, wherein the host cells are grown on microcarriers.

206. (Previously Presented) The method of claim 194, wherein the host cells are provided nutrients by perfusion.

207. (Previously Presented) The method of claim 194, wherein the host cells are provided nutrients by fed batch.

208. (Previously Presented) The method of claim 194, wherein the host cells are provided nutrients by automated roller bottle.

209. (Previously Presented) The method of claim 194, wherein said therapeutic adenovirus composition comprises an adenoviral vector encoding an exogenous gene construct.

210. (Previously Presented) The method of claim 209, wherein said exogenous gene construct is operatively linked to a promoter.

211. (Previously Presented) The method of claim 210, wherein said promoter is SV40 IE, RSV LTR, β -actin, CMV IE, adenovirus major late, polyoma F9-1, or tyrosinase.

212. (Previously Presented) The method of claim 209, wherein said exogenous gene construct encodes a therapeutic gene.

213. (Previously Presented) The method of claim 212, wherein said therapeutic gene encodes antisense *ras*, antisense *myc*, antisense *raf*, antisense *erb*, antisense *src*, antisense *fms*, antisense *jun*, antisense *trk*, antisense *ret*, antisense *gsp*, antisense *hst*, antisense *bcl*, antisense *abl*, Rb, CFTR, p16, p21, p27, p57, p73, C-CAM, APC, CTS-1, *zac1*, scFV *ras*, DCC, NF-1, NF-2, WT-1, MEN-1, MEN II, BRCA1, VHL, MMAC1, FCC, MCC, BRCA2, IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, GM-CSF, G-CSF, thymidine kinase or p53.

214. (Previously Presented) The method of claim 212, wherein said therapeutic gene encodes p53.

215. (Previously Presented) The method of claim 194, wherein said therapeutic adenovirus composition is a replication-incompetent adenovirus.

216. (Previously Presented) The method of claim 215, wherein said replication-incompetent adenovirus composition is lacking at least a portion of the E1-region.

217. (Previously Presented) The method of claim 215, wherein the replication-incompetent adenovirus composition is lacking at least a portion of the E1A and/or E1B region.

218. (Previously Presented) The method of claim 194, wherein said host cells are capable of complementing replication.

219. (Previously Presented) The method of claim 194, wherein said host cells are 293 cells.

220. (Previously Presented) The method of claim 194, wherein said lysate is treated with a nuclease.

221. (Previously Presented) The method of claim 194, wherein said therapeutic adenovirus composition comprises is pharmaceutically acceptable buffer.

222. (Previously Presented) The method of claim 194, wherein said therapeutic adenovirus composition comprises a unit dose of between 10^3 and 10^{15} PFU/dose.

223. (Previously Presented) The method of claim 194, wherein said therapeutic adenovirus commission comprises a unit dose of between 10^{10} and 10^{14} PFU/dose.

224. (Previously Presented) The method of claim 194, wherein said patient is a cancer patient.

225. (Previously Presented) The method of claim 194, wherein the chromatography step is a single chromatography step.

226. (Previously Presented) The method of claim 230, wherein said single chromatography step is anion exchange chromatography.